

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

CONFORMIS, INC.

Plaintiff,

v.

WRIGHT MEDICAL  
TECHNOLOGY, INC. and  
TORNIER, INC.

Defendants.

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Civil Action No. 20-cv-00562-LPS

**JURY TRIAL DEMANDED**

**CONFORMIS’S AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Conformis, Inc. files this Amended Complaint for Patent Infringement against Defendants Wright Medical Technology, Inc. and Tornier, Inc. (collectively “Wright Medical” or “Defendants”) to stop Wright Medical’s willful infringement of Conformis’s patents.

**I. FACTUAL BACKGROUND**

*Conformis’s Revolutionary Technology*

1. Conformis is the world’s leading designer, developer, and manufacturer of patient-specific knee and hip implants as well as the surgical tools to fit those implants into a specific patient’s body. Founded by doctors affiliated with Stanford and Harvard Medical Schools, Conformis began with a revolutionary idea: make the implant fit the patient rather than forcing the patient to fit the implant.

2. For decades before Conformis’s innovation—and continuing today—

implant manufacturers offered surgeons a standard set of implant sizes, akin to the small-medium-large sizing in off-the-rack department stores. This approach forces the surgeon to pick an implant size that appears closest in fit to the patient's anatomy but is not designed for and does not truly fit the individual patient's individual geometry. The surgeon must therefore make size, shape and other compromises to fit the implant as best as possible.

3. These blunt efforts are further hampered by using standard tools to implant standard implants, none of which is designed using the individual patient's anatomy. Because of this imprecise approach, patients often suffer loss of movement and function, instability, and lingering pain after surgery.

4. Conformis recognized that the conventional joint-repair process was backwards: rather than fitting the patient to the implant, the implant should be designed and developed specifically for the patient. This produces a better-fitting implant with an implant shape that feels more natural to the patient because patients vary physiologically in the size, dimensions, shape, position, orientation, and range of motion of their joints.

5. Conformis therefore set out to develop its proprietary iFit® technology to create both patient-specific implants and instruments. Conformis implants are individually sized and shaped to fit each patient's unique anatomy, providing a precise anatomic fit better preserving healthy tissue while leading to increased function and a more natural feel. Conformis patient-specific instrument systems, which use Conformis's iJig® technology, precisely place the patient-specific implant,

reduce surgical time and trauma, and create a reproducible surgical technique. Conformis iJigs eliminate many of the traditional instruments associated with conventional surgery while concurrently simplifying and improving the surgical technique.

6. By combining personalized implants with patient-specific instrumentation, a surgeon can provide treatment that: a) is tailored to the patient; b) preserves more of the patient's joint; and c) minimizes surgical trauma. These patient-specific implant systems fit and work with the individual patient's anatomy.

7. The U.S. Food and Drug Administration has approved Conformis knee- and hip-implant systems for use in the United States. The European Union has approved Conformis knee-implant systems for use in Europe. Conformis currently sells a full line of patient-specific knee- and hip-implant systems in many countries worldwide. To date, Conformis's patient-specific knee and hip implants and customized tools have helped improve the lives of thousands of Americans.

#### *Conformis's Patents*

8. Conformis has developed significant intellectual property associated with its iFit technology, its patient-specific implants, and its iJig patient-specific instruments, including a large portfolio of patents and pending patent applications. These patents and patent applications span a range of related technologies including imaging software, image processing, patient-specific orthopedic implants, patient-specific orthopedic instrumentation, methods of design and manufacture of patient-specific systems, and related surgical techniques. The technology and

patent portfolio are applicable to all major joint systems, including knee, hip, shoulder, and ankle joints.

9. Patent authorities worldwide have recognized that Conformis's patient-specific instrument systems are worthy of patent protection and have granted Conformis over 200 patents on its technologies.

10. On June 11, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,460,304 ("the '304 Patent"), entitled "Joint Arthroplasty Devices and Surgical Tools," to Wolfgang Fitz, Philipp Lang, Daniel Steines, Konstantinos Tsougarakis, and Rene Vargas-Voracek. Conformis is the owner by assignment of the '304 Patent. A copy of the '304 Patent is attached hereto as Exhibit A.

11. On March 29, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,295,482 ("the '482 Patent"), entitled "Patient Selectable Joint Arthroplasty Devices and Surgical Tools," to Wolfgang Fitz, Philipp Lang, Raymond Bojarski, and Daniel Steines. Conformis is the owner by assignment of the '482 Patent. A copy of the '482 Patent is attached hereto as Exhibit B.

12. On January 7, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,623,026 ("the '026 Patent"), entitled "Patient Selectable Joint Arthroplasty Devices and Surgical Tools Incorporating Surgical Relief," to Terrence Wong, Raymond Bojarski, Daniel Steines, and Philipp Lang. Conformis is the owner by assignment of the '026 Patent. A copy of the '026 Patent

is attached hereto as Exhibit C.

13. On May 3, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,326,780 (“the ’780 Patent”), entitled “Patient Selectable Joint Arthroplasty Devices and Surgical Tools Incorporating Anatomical Relief,” to Terrence Wong, Raymond Bojarski, Daniel Steines, and Philipp Lang. Conformis is the owner by assignment of the ’780 Patent. A copy of the ’780 Patent is attached hereto as Exhibit D.

14. Collectively, the ’304, ’482, ’026, and ’780 Patents are the “Conformis Patents.”

*Wright Medical’s Past Infringement*

15. This is not the first time Wright Medical has copied Conformis’s innovative approach and infringed its patents.

16. In 2013, Conformis was forced to sue Wright Medical Group, Inc. and Wright Medical Technology, Inc. (collectively, “Wright”) for patent infringement because Wright’s PROPHECY Pre-Operative Navigation Guides and PROPHECY INBONE Pre-Operative Navigation System patient-specific instruments infringed fundamental aspects of Conformis’s patent portfolio. *See Conformis, Inc. v. Wright Medical Tech., Inc.*, Civil Action No. 1:13-cv-12312 (D. Mass.) (First Am. Compl., D.I. 31).

17. One of the patents Conformis asserted against Wright in the 2013 case was the ’304 Patent. *Id.*

18. The parties settled that lawsuit in April 2015. As part of the parties’

settlement, Conformis granted Wright and its affiliates a license to Conformis's patent portfolio (the "2015 License Agreement," *see* [https://www.sec.gov/Archives/edgar/data/1305773/000104746915005363/a2224951zex-10\\_33.htm](https://www.sec.gov/Archives/edgar/data/1305773/000104746915005363/a2224951zex-10_33.htm)). The 2015 License Agreement, however, was restricted to the use of patient-specific instrumentation for implanting non-patient-specific devices in the foot or ankle. The license did not grant Wright any right to use Conformis's patented technology in the field of upper extremities, such as shoulders.

*Wright Medical's Merger with Tornier*

19. While Wright was negotiating to settle Conformis's infringement claims, it was also negotiating to merge with Tornier, N.V., a manufacturer of patient-specific instrumentation for use in upper extremities, such as shoulders. Wright completed its merger with Tornier in October 2015. Tornier began selling its BLUEPRINT line of patient-specific instruments (described below) in 2014 and Wright Medical has been selling them to this day.

*Wright Medical's Infringing Activities*

20. Wright Medical offers a line of shoulder arthroplasty systems (the "Accused Systems") that include patient-specific instruments ("PSI") for use with their shoulder implants. *See generally* Exs. E–L. Wright Medical markets these patient-specific instruments as their BLUEPRINT 3d Planning + PSI products (the "Accused Shoulder Instruments") along with associated shoulder implants, such as, e.g., the AEQUALIS™ series, including AEQUALIS™ PERFORM, AEQUALIS™ PERFORM+, AEQUALIS™ REVERSED, and AEQUALIS™ REVERSED II

implants (the “Accused Shoulder Implants”).

21. In the 2018 Wright Medical Group, N.V. Annual Report, Wright Medical CEO Robert J. Palmisano explained that the BLUEPRINT system gave Wright Medical “significant competitive advantages”:

**BLUEPRINT™ Surgeon Controlled 3D Planning Software.**

We believe our BLUEPRINT™ software technology represents the future and offers significant pipeline opportunities to fuel organic growth. We see BLUEPRINT™ as the foundation for a comprehensive digital ecosystem—a strong enabling technology that offers us significant competitive advantages. In 2018, we saw a large increase in surgeon use with case penetration increasing from 20% in Q2 to 40% by the end of Q4.

See <http://ir.wright.com/static-files/22a410b6-cf24-4f7c-b2b3-88f0efdff009> at 3.

## II. THE PARTIES

22. Plaintiff Conformis, Inc. is incorporated in Delaware with its worldwide headquarters at 600 Technology Park Drive, Billerica, MA 01730.

23. Defendant Wright Medical Technology, Inc. is incorporated in Delaware with its principal place of business at 1023 Cherry Road, Memphis, TN 38117.

24. Defendant Tornier, Inc. is incorporated in Delaware with its principal place of business at 10801 Nesbitt Avenue South, Bloomington, MN 55437.

## III. JURISDICTION AND VENUE

25. This Court has subject-matter jurisdiction over Conformis’s claims under 28 U.S.C. §§ 1331 and 1338(a) because those claims arise under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*

26. This Court has personal jurisdiction over Defendants, at least because

Defendants are at home in the State of Delaware, where they are incorporated and have a registered agent for service of process. In addition, Defendants regularly do or solicit business in the State of Delaware and have committed one or more acts of patent infringement in the District of Delaware.

27. Venue in this Court is proper under the provisions of 28 U.S.C. §§ 1391(b) and (c) and 1400. Defendants are incorporated in Delaware and thus reside in this State.

#### **IV. FIRST CLAIM FOR RELIEF**

##### **(Infringement of the '304 Patent)**

28. Conformis incorporates by reference Paragraphs 1 through 27, inclusive, as though fully set forth in this Paragraph.

29. Wright Medical has in the past and is presently making, using, offering for sale, and/or selling a patient-specific system for shoulder surgery that directly infringes one or more claims of the '304 Patent, literally or under the doctrine of equivalents.

30. At least some of the Accused Shoulder Instruments, including Wright Medical's BLUEPRINT 3D Planning + PSI system (Titanium version), practice at least one claim of the '304 Patent. For example, claim 1 recites:

A surgical instrument for use in surgically repairing a joint of a patient, the surgical instrument comprising:

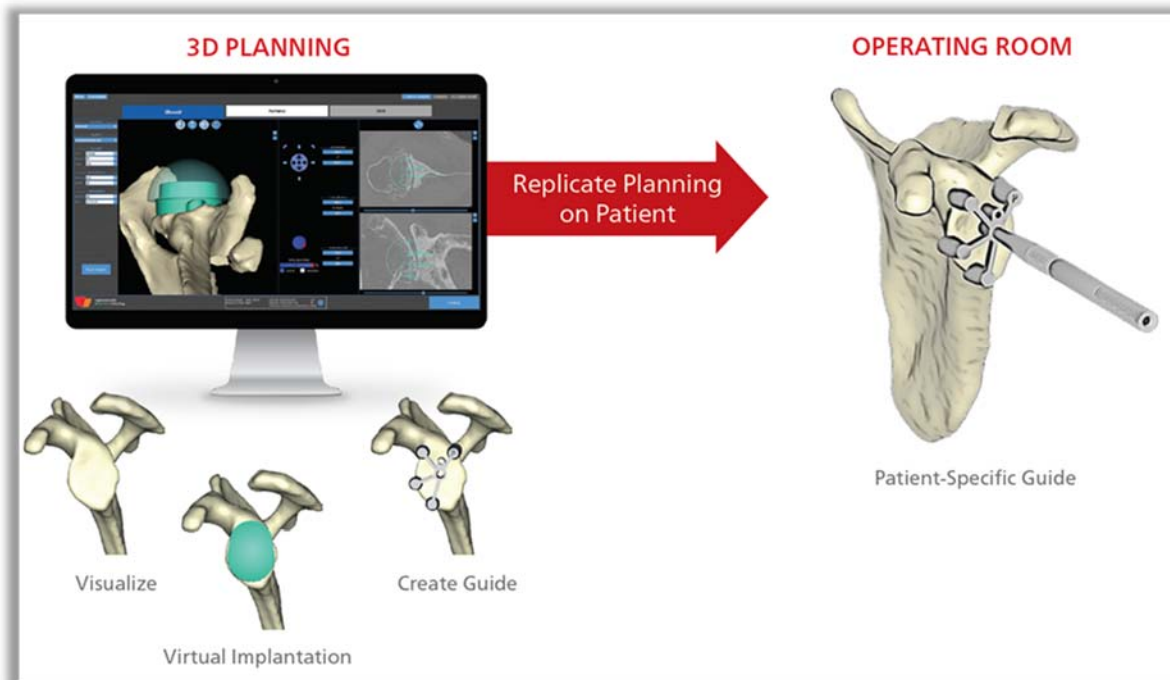
a mold having an internal surface that includes joint information derived from image data of the joint of the patient; and

two or more guide holes, each configured to guide a surgical pin, wherein at least one of the two or more guide holes has a position based on anatomical information of the joint of the patient to facilitate the placement

of an articular repair system when the internal surface of the mold is aligned with the joint of the patient, wherein the articular repair system has a predetermined rotation angle and wherein the position is based on the predetermined rotation angle.

Ex. A at Claim 1.

31. Wright Medical's BLUEPRINT 3D Planning + PSI system (Titanium version) is marketed as a system for "pre-operative planning" and "generat[ing] patient-specific instrumentation (PSI)." Ex. F at 4. Claim 1 of the '304 Patent recites "a surgical instrument for use in surgically repairing a joint," comprising "a mold having an internal surface that includes joint information derived from image data of the joint" and "two or more guide holes, each configured to guide a surgical pin." Ex. A at Claim 1. The BLUEPRINT Titanium system generates a "patient specific guide," also referred to as a "3D PSI guide" based on joint image data:



Ex. F. at 4, 6.

32. Claim 1 of the '304 Patent also recites that “at least one of the two or more guide holes has a position based on anatomical information of the joint of the patient to facilitate the placement of an articular repair system when the internal surface of the mold is aligned with the joint of the patient, wherein the articular repair system has a predetermined rotation angle and wherein the position is based on the predetermined rotation angle.” Ex. A at Claim 1. The BLUEPRINT Titanium system involves planning software to “[s]elect and place the glenoid component in order to get an appropriate position,” with positioning parameters including version, inclination, position (antero-posterior, supero-inferior, implant rotation), and medialization or lateralization, among other parameters. Ex. F. at 5. This planning includes setting the positioning of the implant, as well as a rotation angle, which is set based on the patient’s anatomical information. The BLUEPRINT Titanium system also involves using the PSI guide to place a rotational marker for the final implant. Ex. F at 8. This positioning is based at least in part on the predetermined rotation angle.

33. A more detailed analysis of Wright Medical’s direct infringement of the '304 Patent can be found in Exhibit M which is incorporated in its entirety as if set forth herein.

34. Wright Medical has also actively induced, and continues to actively induce, others to infringe at least claim 1 of the '304 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 1 of the '304 Patent by making, using, offering to sell, selling,

and/or importing in and into the United States the Accused Shoulder Instruments, as detailed above.

35. Wright Medical knew about the '304 Patent since at least 2013, when Conformis sued Wright for infringing the '304 Patent. Wright Medical also knows that the 2015 License Agreement includes limited rights to practice the '304 Patent. Further, under the 2015 License Agreement, Wright Medical must mark its licensed products with all applicable Conformis patent numbers. Therefore, Wright Medical has a contractual duty to understand Conformis's patents, including the '304 Patent, and determine whether its products are covered by the '304 Patent.

36. Wright Medical knows the 2015 License Agreement did not grant Wright Medical any right to use Conformis's patented technology in the field of upper extremities, such as shoulders and that the 2015 License Agreement was restricted to the use of patient-specific instrumentation for implanting non-patient-specific devices in the foot or ankle. Therefore, Wright Medical knows that its use of the '304 Patent's technology in the Accused Shoulder Instruments—which are designed, marketed, and sold for use with shoulder implants—is outside the scope of the 2015 License Agreement, and therefore infringes the '304 Patent. And because Wright Medical knows its own use infringes, it also knows that its customers' use infringes.

37. At a minimum, Wright Medical has known since Conformis filed its original Complaint that its Accused Shoulder Instruments infringed the '304 Patent, and therefore that its customers' use of the Accused Shoulder Instruments

is also infringing.

38. Wright Medical's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the Accused Shoulder Instruments, providing instructions on how to use the Accused Shoulder Instruments, and promoting the use of the Accused Shoulder Instruments. For example, Wright Medical has encouraged and/or will encourage customers and end users to use the Accused Shoulder Instruments by means of marketing materials and videos, including the ten brochures and eighteen videos found at <https://www.shoulderblueprint.com/literature-videos/>, a "micro-site" specific to the Accused Systems that is accessible from Wright Medical's website.

39. Wright Medical also has instructed and/or will instruct customers on how to use the Accused Shoulder Instruments by means of product manuals. For example, Wright Medical's website includes a "Virtual Learning Center—An Educational Platform for Surgeons" that Wright Medical describes as a "procedural reference library with educational videos and technique insights" about how to use the Accused Shoulder Instruments. According to its website, Wright Medical also offers mobile surgical training in an RV that travels to its customers offering "expertly led education, training and product demonstrations." These resources provided customers with detailed explanations and instructions about how to use the Accused Shoulder Instruments and promote and demonstrate how to use the Accused Shoulder Instruments—including video footage of surgical procedures using the Accused Shoulder Instruments—in a manner that would infringe.

40. Wright Medical has also contributed, and continues to contribute, to its customers' and end users' direct infringement of the '304 Patent in violation of 35 U.S.C. § 271(c) by providing the Accused Shoulder Instruments. The Accused Shoulder Instruments are specially made using joint information derived from image data of an individual patient's joint. Such individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 1 of the '304 Patent.

41. Conformis has suffered economic harm because of Wright Medical's infringing activities in an amount to be proven at trial, but in no case less than a reasonably royalty.

42. Wright Medical's acts have caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to Conformis for which there is no adequate remedy at law. Unless enjoined by this Court, Wright Medical will continue to infringe the '304 Patent.

## **V. SECOND CLAIM FOR RELIEF**

### **(Infringement of the '482 Patent)**

43. Conformis incorporates by reference Paragraphs 1 through 42, inclusive, as though fully set forth in this Paragraph.

44. Wright Medical has in the past and is presently making, using, offering for sale, and/or selling a patient-specific system for shoulder surgery that directly infringes one or more claims of the '482 Patent, literally or under the

doctrine of equivalents.

45. The Accused Systems practice at least one claim of the '482 Patent.

For example, claim 13 recites:

A joint arthroplasty system for use in surgically repairing a diseased or damaged joint of a patient, comprising:

an implant; and

a block having a patient-specific surface and a guide:

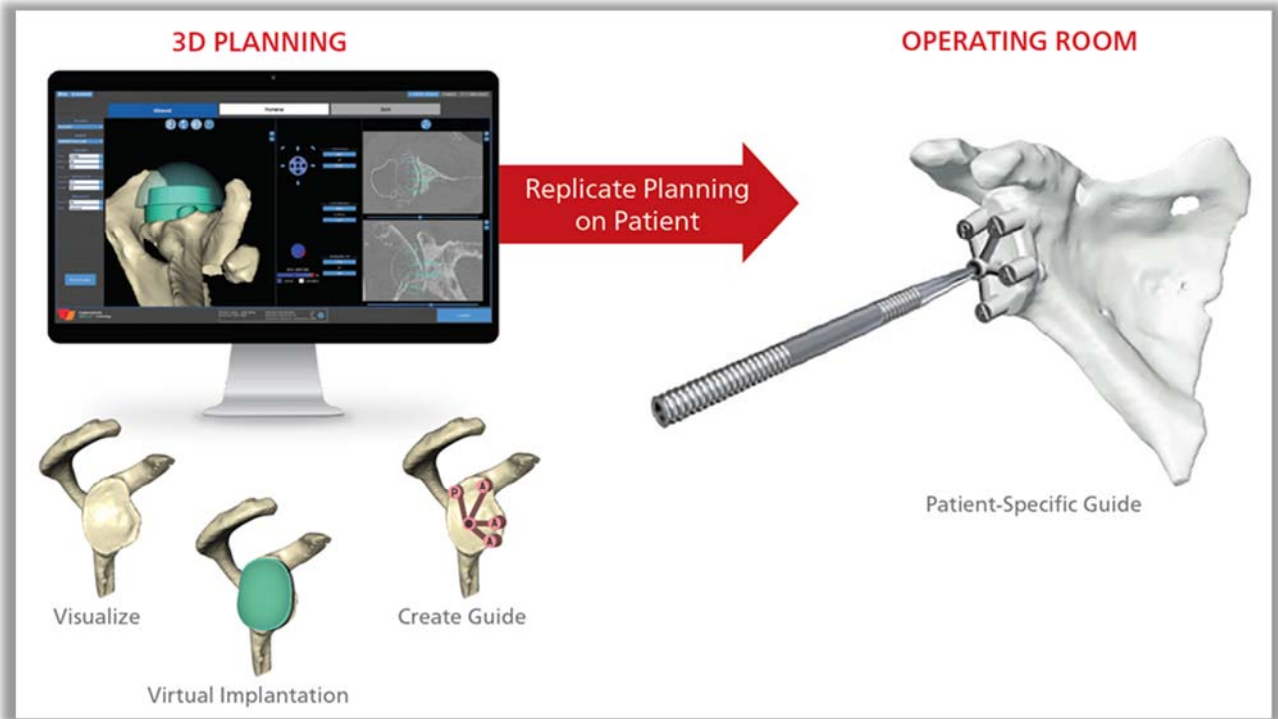
the patient-specific surface having a first portion configured to have a shape that is substantially a negative of a subchondral bone surface of the diseased or damaged joint and a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint, wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint; and

the guide being sized and shaped to accommodate a surgical tool and have a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint.

Ex. B at Claim 13.

46. As an example of an Accused System, Wright Medical's BLUEPRINT 3D Planning + PSI system (Polyamide version) is marketed as a system for "pre-operative planning" and "generat[ing] patient-specific instrumentation (PSI)." Ex. E at 4. The described "glenoid guide" (PSI) is for use with "[a]ll implants," *id.* at 9 (the Accused Shoulder Implants). Claim 13 of the '482 Patent recites "a joint arthroplasty system" comprising "an implant" and "a block having a patient-specific surface and a guide." Ex. B at Claim 13. The BLUEPRINT Polyamide system involves "position[ing] the various implants and understand[ing] the appropriate path of treatment based on the patient's anatomy" in the context of shoulder

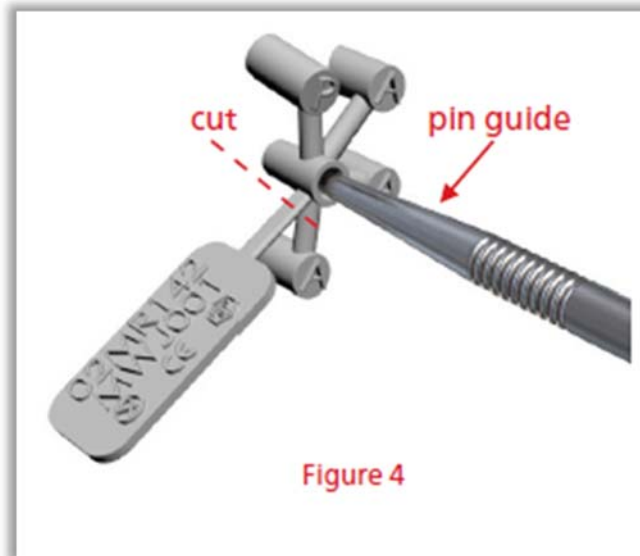
arthroplasty. Ex. E at 4. The BLUEPRINT Polyamide system generates a “patient specific guide,” also referred to as a “3D PSI guide” based on joint image data:



Ex. E at 4, 6.

47. Claim 13 also recites “the patient-specific surface having a first portion configured to have a shape that is substantially a negative of a subchondral bone surface of the diseased or damaged joint and a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint, wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint” and “the guide being sized and shaped to accommodate a surgical tool and have a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint.” Ex. B at Claim 13. The

PSI guide generated by the BLUEPRINT Polyamide system “references the patients’ operative glenoid bone” and requires osteophytes to be preserved “in order to ensure a good fit of the guide.” Ex. E at 8. Portions of the surface of the guide are substantially a negative of the subchondral bone, and portions are substantially a negative of a cortical bone surface. Further, the PSI guide of the BLUEPRINT Polyamide system includes a guide portion configured to guide surgical tools such as the guide pin and pin guide:



Ex. E at 7.

48. Wright Medical’s BLUEPRINT Titanium system along with its associated shoulder implant infringes the ’482 Patent in a similar manner. Ex. F at 4–8.

49. A more detailed analysis of Wright Medical’s direct infringement of the ’482 Patent can be found in Exhibit N which is incorporated in its entirety as if set forth herein. The Titanium system functions in a manner substantially similar to

that of the Polyamide system, as reflected in Exhibit N. *See also* Exs. J, K.

50. Wright Medical has also actively induced, and continues to actively induce, others to infringe at least claim 13 of the '482 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 13 of the '482 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the Accused Systems, as detailed above.

51. The 2015 License Agreement gives Wright Medical a license to certain of Conformis's patents, including the '482 Patent, to make products for certain foot or ankle surgeries and treatments using PSI. As a Conformis licensee, it was in Wright Medical's interest to ensure it was aware of all patents owned by or issued to Conformis, especially those relating to PSI. Further, under the 2015 License Agreement, Wright Medical must mark its licensed products with all applicable Conformis patent numbers. Therefore, Wright Medical has a contractual duty to understand Conformis's patents, including the '482 Patent, and determine whether its products are covered by the '482 Patent.

52. Wright Medical also knows that the 2015 License Agreement covers the '482 Patent and that the 2015 License Agreement was restricted to the use of PSI for implanting non-patient-specific devices in the foot or ankle. Further, Wright Medical knows the 2015 License Agreement did not grant Wright Medical any right to use Conformis's patented technology in the field of upper extremities, such as shoulders. Therefore, Wright Medical knows that its use of the '482 Patent's

technology in the Accused Systems—which are designed, marketed, and sold for use with shoulder implants—is outside the scope of the 2015 License Agreement, and therefore infringes the '482 Patent. And because Wright Medical knows its own use infringes, it also knows that its customers' use infringes.

53. Further, Wright Medical has been aware of the '482 Patent since at least March of 2019, when Wright Medical's affiliate, Tornier SAS, submitted an information disclosure statement in United States Patent Application No. 15/024747, which application eventually issued as U.S. Patent No. 10,405,993 ("Tornier's '993 Patent). That information disclosure statement listed the '482 Patent. The examiner considered the '482 Patent when examining Tornier's '993 Patent.

54. At a minimum, Wright Medical has known since Conformis filed its original Complaint that its Accused Systems infringed the '482 Patent, and therefore that its customers' use of the Accused Systems is also infringing.

55. Wright Medical's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the Accused Systems, providing instructions on how to use the Accused Systems, and promoting the use of the Accused Systems. For example, Wright Medical has encouraged and/or will encourage customers and end users to use the Accused Systems by means of marketing materials and videos, including the ten brochures and eighteen videos found at <https://www.shoulderblueprint.com/literature-videos/>, a "micro-site" specific to the Accused Systems that is accessible from Wright

Medical's website.

56. Wright Medical also has instructed and/or will instruct customers on how to use the Accused Systems by means of product manuals. For example, Wright Medical's website includes a "Virtual Learning Center—An Educational Platform for Surgeons" that Wright Medical describes as a "procedural reference library with educational videos and technique insights" about how to use the Accused Systems. These resources provided customers with detailed explanations and instructions about how to use the Accused Systems and promote and demonstrate how to use the Accused Systems—including video footage of surgical procedures using the Accused Systems—in a manner that would infringe. According to its website, Wright Medical also offers mobile surgical training in an RV that travels to its customers offering "expertly led education, training and product demonstrations."

57. Wright Medical has also contributed, and continues to contribute, to its customers' and end users' direct infringement of the '482 Patent in violation of 35 U.S.C. § 271(c) by providing the Accused Systems. The Accused Systems contain a "patient-specific surface" which is configured to be the negative of the patient's bone surface. Such individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 13 of the '482 Patent.

58. Conformis has suffered economic harm because of Wright Medical's infringing activities in an amount to be proven at trial, but in no case less than a reasonably royalty.

59. Wright Medical's acts have caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to Conformis for which there is no adequate remedy at law. Unless enjoined by this Court, Wright Medical will continue to infringe the '482 Patent.

## **VI. THIRD CLAIM FOR RELIEF**

### **(Infringement of the '026 Patent)**

60. Conformis incorporates by reference Paragraphs 1 through 59, inclusive, as though fully set forth in this Paragraph.

61. Wright Medical has in the past and is presently making, using, offering for sale, and/or selling a patient-specific system for shoulder surgery that directly infringes one or more claims of the '026 Patent, literally or under the doctrine of equivalents.

62. The Accused Systems practice at least one claim of the '026 Patent. For example, claim 15 recites:

A system for joint arthroplasty, the system comprising:

a first template, the first template including:

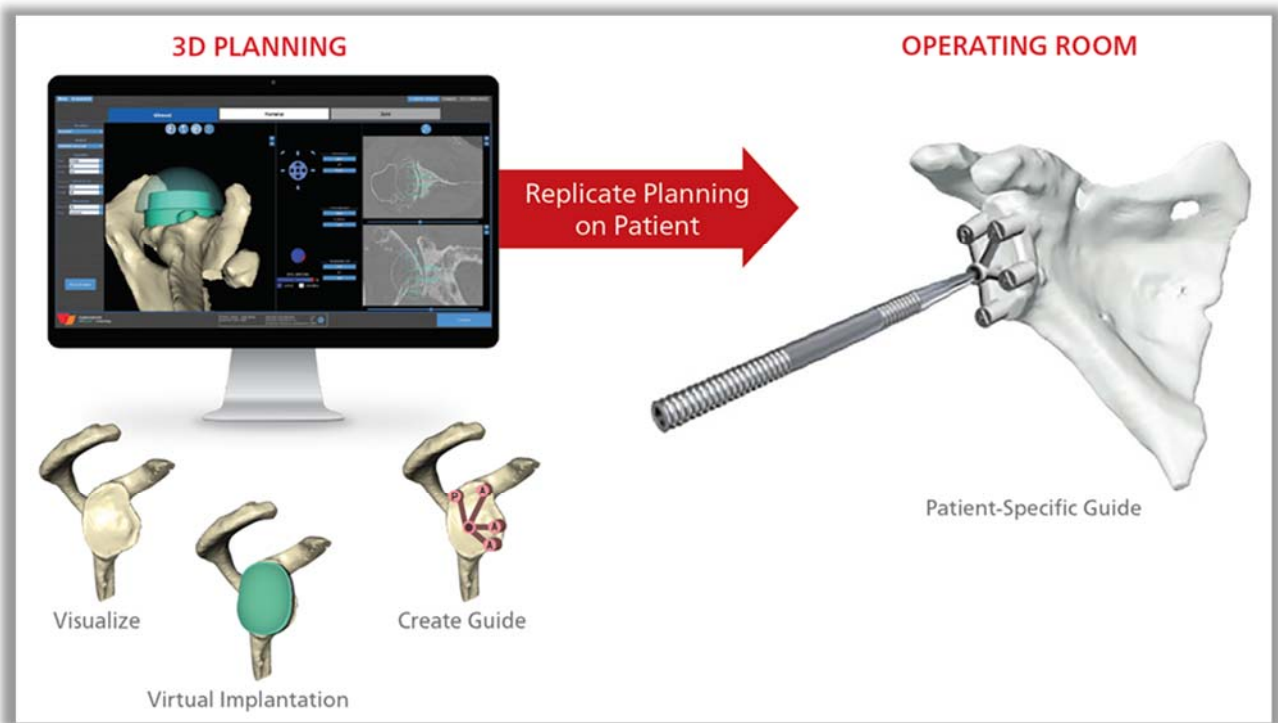
at least one surface for engaging a first articular surface of a joint, the at least one surface being substantially a negative of portions or all of the first articular surface; at least a portion of the at least one surface further including an anatomical relief; and

at least one guide for directing movement of a surgical instrument; and wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.

Ex. C at Claim 15.

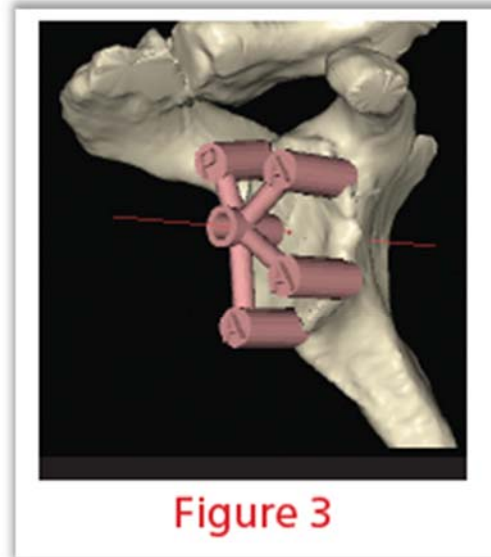
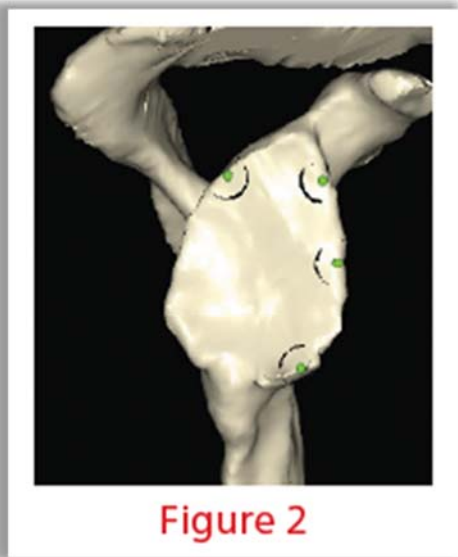
63. As an example of an Accused System, Wright Medical's BLUEPRINT

3D Planning + PSI system (Polyamide version) is marketed as a system for “pre-operative planning” and “generat[ing] patient-specific instrumentation (PSI).” Ex. E at 4. Claim 15 of the ’026 Patent recites “a system for joint arthroplasty” comprising “a first template” that includes “at least one surface for engaging a first articular surface of a joint, the at least one surface being substantially a negative of portions or all of the first articular surface; at least a portion of the at least one surface further including an anatomical relief.” Ex. C at Claim 15. The BLUEPRINT Polyamide system generates a “patient specific guide,” also referred to as a “3D PSI guide” based on joint image data:



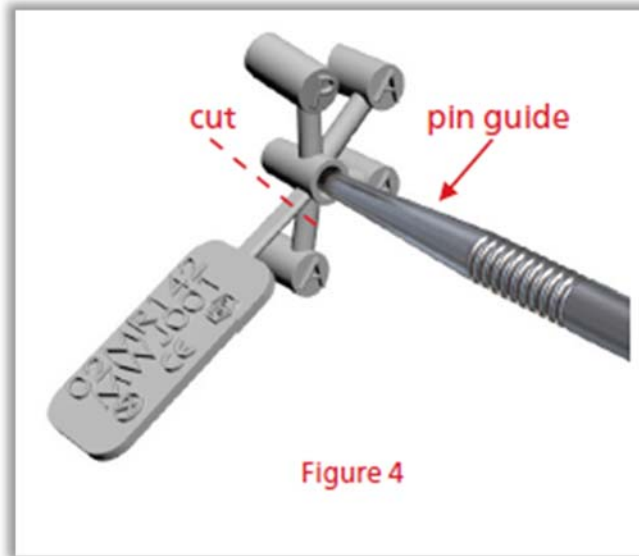
Ex. E at 4, 6. The BLUEPRINT Polyamide system documentation states that “[o]steophytes must be kept in order to ensure a good fit of the guide.” Ex. E at 8. The 3D PSI guide of the BLUEPRINT Polyamide system includes a surface that is

substantially a negative of at least portions of an articular surface, with at least one surface including an anatomical relief:



Ex. E at 6.

64. Claim 15 also recites “at least one guide for directing movement of a surgical instrument; and wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.” Ex. C at Claim 15. The PSI guide of the BLUEPRINT Polyamide system includes a guide portion configured to guide surgical tools such as the guide pin and pin guide:



Ex. E at 7. Further, the BLUEPRINT Polyamide system involves planning software to “virtually position the various implants and understand the appropriate path of treatment based on the patient’s anatomy,” including “[p]lanning correction of glenoid version and inclination.” Ex. E. at 4. This planning includes setting an orientation relative to an anatomical or a biomechanical axis associated with the joint.

65. Wright Medical’s BLUEPRINT Titanium system infringes the ’026 Patent in a similar manner. Ex. F at 4–8.

66. A more detailed analysis of Wright Medical’s direct infringement of the ’026 Patent can be found in Exhibit O which is incorporated in its entirety as if set forth herein. The Titanium system functions in a manner substantially similar to that of the Polyamide system, as reflected in Exhibit O. *See also* Exs. J, K.

67. Wright Medical has also actively induced, and continues to actively induce, others to infringe at least claim 15 of the ’026 Patent in violation of 35

U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 15 of the '026 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the Accused Systems, as detailed above.

68. The 2015 License Agreement gives Wright Medical a license to certain of Conformis's patents, including the '026 Patent, to make products for certain foot or ankle surgeries and treatments using PSI. As a Conformis licensee, it was in Wright Medical's interest to ensure it was aware of all patents owned by or issued to Conformis, especially those relating to PSI. Further, under the 2015 License Agreement, Wright Medical must mark its licensed products with all applicable Conformis patent numbers. Therefore, Wright Medical has a contractual duty to understand Conformis's patents, including the '026 Patent, and determine whether its products are covered by the '026 Patent.

69. Wright Medical also knows that the 2015 License Agreement covers the '026 Patent and that the 2015 License Agreement was restricted to the use of PSI for implanting non-patient-specific devices in the foot or ankle. Further, Wright Medical knows the 2015 License Agreement did not grant Wright Medical any right to use Conformis's patented technology in the field of upper extremities, such as shoulders. Therefore, Wright Medical knows that its use of the '026 Patent's technology in the Accused Systems—which are designed, marketed, and sold for use with shoulder implants—is outside the scope of the 2015 License Agreement, and therefore infringes the '026 Patent. And because Wright Medical knows its own use

infringes, it also knows that its customers' use infringes.

70. Further, Wright Medical has been aware of the '026 Patent since at least March of 2019, when Wright Medical's affiliate, Tornier SAS, submitted an information disclosure statement in United States Patent Application No. 15/024747, which application eventually issued as Tornier's '993 Patent. That information disclosure statement listed the '026 Patent. The examiner considered the '026 Patent when examining Tornier's '993 Patent.

71. At a minimum, Wright Medical has known since Conformis filed its original Complaint that its Accused Systems infringed the '026 Patent, and therefore that its customers' use of the Accused Systems is also infringing.

72. Wright Medical's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the Accused Systems, providing instructions on how to use the Accused Systems, and promoting the use of the Accused Systems. For example, Wright Medical has encouraged and/or will encourage customers and end users to use the Accused Systems by means of marketing materials and videos, including the ten brochures and eighteen videos found at <https://www.shoulderblueprint.com/literature-videos/>, a "micro-site" specific to the Accused Systems that is accessible from Wright Medical's website.

73. Wright Medical also has instructed and/or will instruct customers on how to use the Accused Systems by means of product manuals. For example, Wright Medical's website includes a "Virtual Learning Center—An Educational Platform

for Surgeons” that Wright Medical describes as a “procedural reference library with educational videos and technique insights” about how to use the Accused Shoulder Instruments. These resources provided customers with detailed explanations and instructions about how to use the Accused Shoulder Instruments and promote and demonstrate how to use the Accused Shoulder Instruments—including video footage of surgical procedures using the Accused Shoulder Instruments—in a manner that would infringe. According to its website, Wright Medical also offers mobile surgical training in an RV that travels to its customers offering “expertly led education, training and product demonstrations.”

74. Wright Medical has also contributed, and continues to contribute, to its customers’ and end users’ direct infringement of the ’026 Patent in violation of 35 U.S.C. § 271(c) by providing the Accused Systems. The Accused Systems include a template with a surface that include an anatomical relief and include a guide with an orientation that is predetermined to an anatomical or biomechanical axis. Such individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 15 of the ’026 Patent.

75. Conformis has suffered economic harm because of Wright Medical’s infringing activities in an amount to be proven at trial, but in no case less than a reasonably royalty.

76. Wright Medical’s acts have caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to Conformis for which there

is no adequate remedy at law. Unless enjoined by this Court, Wright Medical will continue to infringe the '026 Patent.

## **VII. FOURTH CLAIM FOR RELIEF**

### **(Infringement of the '780 Patent)**

77. Conformis incorporates by reference Paragraphs 1 through 76, inclusive, as though fully set forth in this Paragraph.

78. Wright Medical has in the past and is presently making, using, offering for sale, and/or selling a patient-specific system for shoulder surgery that directly infringes one or more claims of the '780 Patent, literally or under the doctrine of equivalents.

79. The Accused Systems practice at least one claim of the '780 Patent. For example, claim 1 recites:

A system for joint arthroplasty for repairing a joint of a patient, the system comprising:

a first template, the first template including:

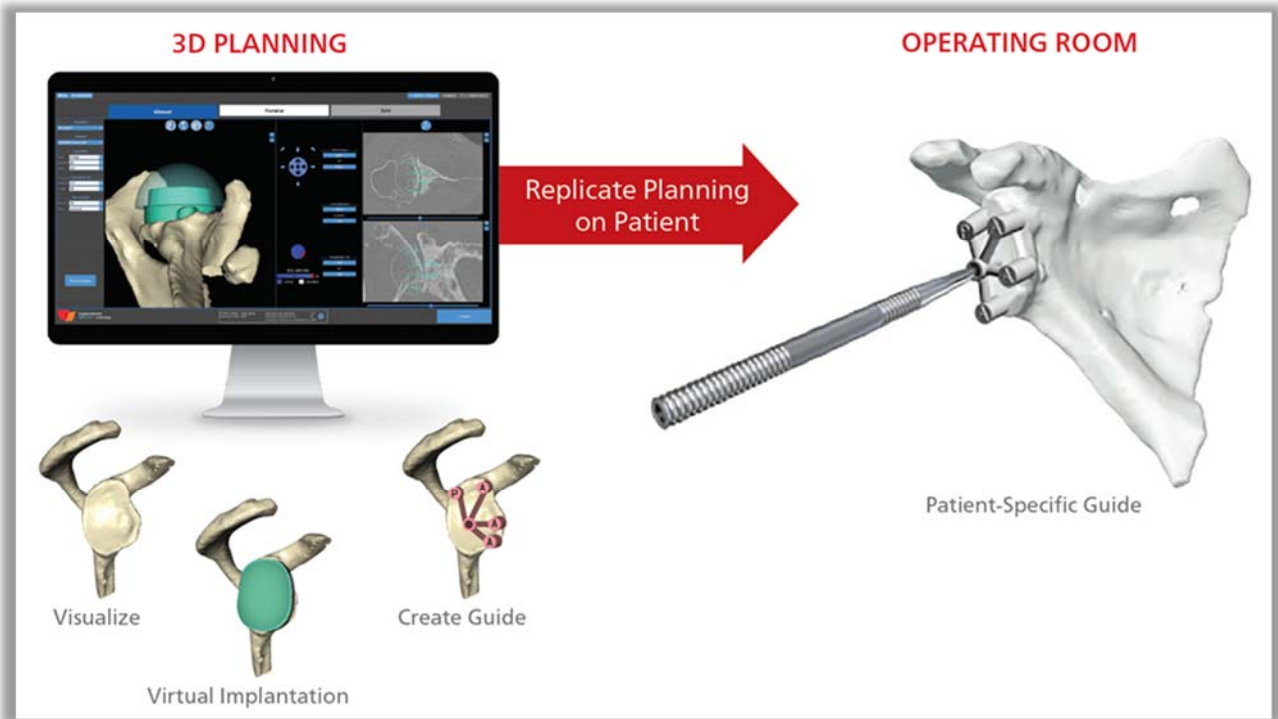
a contact surface for engaging a first articular surface of the joint of the patient, the contact surface including shape information derived from electronic image data of at least a portion of the first articular surface; at least a relieved portion of the contact surface further including an anatomical relief configured such that when the contact surface engages the first articular surface, the relieved portion does not engage an anatomical structure of the first articular surface; and

at least one guide for directing movement of a surgical instrument; and

wherein the guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis associated with the joint of the patient.

Ex. D at Claim 1.

80. As an example of an Accused System, Wright Medical's BLUEPRINT 3D Planning + PSI system (Polyamide version) is marketed as a system for "pre-operative planning" and "generat[ing] patient-specific instrumentation (PSI)." Ex. E at 4. Claim 1 of the '780 Patent recites "a system for joint arthroplasty" comprising "a first template" that includes "a contact surface for engaging a first articular surface of the joint of the patient, the contact surface including shape information derived from electronic image data of at least a portion of the first articular surface; at least a relieved portion of the contact surface further including an anatomical relief configured such that when the contact surface engages the first articular surface, the relieved portion does not engage an anatomical structure of the first articular surface." Ex. D at Claim 1. The BLUEPRINT Polyamide system generates a "patient specific guide," also referred to as a "3D PSI guide" based on joint image data:



Ex. E at 4, 6. The BLUEPRINT Polyamide system documentation states that “[o]steophytes must be kept in order to ensure a good fit of the guide.” Ex. E at 8.

81. At least a portion of the surface includes an anatomical relief that does not engage an anatomical structure:

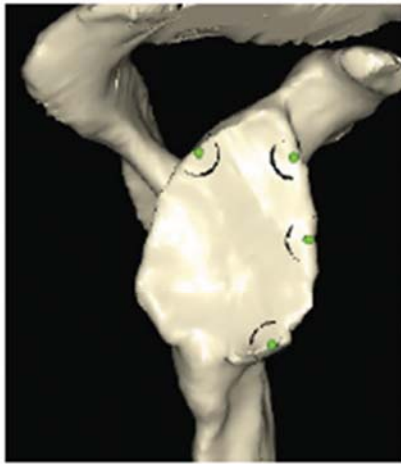


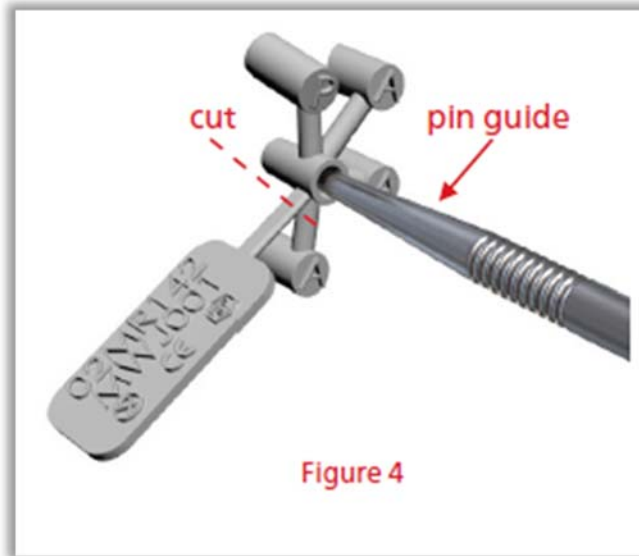
Figure 2



Figure 3

Ex. E at 6.

82. Claim 1 also recites “at least one guide for directing movement of a surgical instrument” and “wherein the guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis associated with the joint of the patient.” Ex. D at Claim 1. The PSI guide of the BLUEPRINT Polyamide system includes a guide member centrally located within the guide block. The opening of the central guide member is configured to guide surgical tools such as pin guide and the guide pin:



Ex. E at 7. Further, the BLUEPRINT Polyamide system involves planning software to “virtually position the various implants and understand the appropriate path of treatment based on the patient’s anatomy,” including “[p]lanning correction of glenoid version and inclination.” Ex. E. at 4. This planning includes setting an orientation relative to an anatomical or a biomechanical axis associated with the patient.

83. Wright Medical’s BLUEPRINT Titanium system infringes the ’780 Patent in a similar manner. Ex. F at 4–8.

84. A more detailed analysis of Wright Medical’s direct infringement of the ’780 Patent can be found in Exhibit P which is incorporated in its entirety as if set forth herein. The Titanium system functions in a manner substantially similar to that of the Polyamide system, as reflected in Exhibit P. *See also* Exs. J, K.

85. Wright Medical has also actively induced, and continues to actively induce, others to infringe at least claim 1 of the ’780 Patent in violation of 35 U.S.C.

§ 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 1 of the '780 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the Accused Systems, as detailed above.

86. The 2015 License Agreement gives Wright Medical a license to certain of Conformis's patents, including the '780 Patent, to make products for certain foot or ankle surgeries and treatments using PSI. As a Conformis licensee, it was in Wright Medical's interest to ensure it was aware of all patents owned by or issued to Conformis, especially those relating to PSI. Further, under the 2015 License Agreement, Wright Medical must mark its licensed products with all applicable Conformis patent numbers. Therefore, Wright Medical has a contractual duty to understand Conformis's patents, including the '780 Patent, and determine whether its products are covered by the '780 Patent.

87. Wright Medical also knows that the 2015 License Agreement covers the '780 Patent and that the 2015 License Agreement was restricted to the use of PSI for implanting non-patient-specific devices in the foot or ankle. Further, Wright Medical knows the 2015 License Agreement did not grant Wright Medical any right to use Conformis's patented technology in the field of upper extremities, such as shoulders. Therefore, Wright Medical knows that its use of the '780 Patent's technology in the Accused Systems—which are designed, marketed, and sold for use with shoulder implants—is outside the scope of the 2015 License Agreement, and therefore infringes the '780 Patent. And because Wright Medical knows its own use

infringes, it also knows that its customers' use infringes.

88. Further, Wright Medical has been aware of the '780 Patent since at least March of 2019, when Wright Medical's affiliate, Tornier SAS, submitted an information disclosure statement in United States Patent Application No. 15/024747, which application eventually issued as Tornier's '993 Patent. That information disclosure statement listed the '780 Patent. The examiner considered the '780 Patent when examining Tornier's '993 Patent.

89. At a minimum, Wright Medical has known since Conformis filed its original Complaint that its Accused Systems infringed the '780 Patent, and therefore that its customers' use of the Accused Systems is also infringing.

90. Wright Medical's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the Systems, providing instructions on how to use the Accused Systems, and promoting the use of the Accused Systems. For example, Wright Medical has encouraged and/or will encourage customers and end users to use the Accused Systems by means of marketing materials and videos, including the ten brochures and eighteen videos found at <https://www.shoulderblueprint.com/literature-videos/>, a "micro-site" specific to the Accused Systems that is accessible from Wright Medical's website.

91. Wright Medical also has instructed and/or will instruct customers on how to use the Accused Systems by means of product manuals. For example, Wright Medical's website includes a "Virtual Learning Center—An Educational Platform for Surgeons" that Wright Medical describes as a "procedural reference library with

educational videos and technique insights” about how to use the Accused Systems. These resources provided customers with detailed explanations and instructions about how to use the Accused Systems and promote and demonstrate how to use the Accused Systems—including video footage of surgical procedures using the Accused Systems—in a manner that would infringe. According to its website, Wright Medical also offers mobile surgical training in an RV that travels to its customers offering “expertly led education, training and product demonstrations.”

92. Wright Medical has also contributed, and continues to contribute, to its customers’ and end users’ direct infringement of the ’780 Patent in violation of 35 U.S.C. § 271(c) by providing the Accused Systems. The Accused Systems include a template including shape information derived from electronic image data of at least a portion of a patient’s joint. Such individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 1 of the ’780 Patent.

93. Conformis has suffered economic harm because of Wright Medical’s infringing activities in an amount to be proven at trial, but in no case less than a reasonably royalty.

94. Wright Medical’s acts have caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to Conformis for which there is no adequate remedy at law. Unless enjoined by this Court, Wright Medical will continue to infringe the ’780 Patent.

### **VIII. WILLFUL INFRINGEMENT**

95. Conformis incorporates by reference Paragraphs 1 through 94, inclusive, as though fully set forth in this Paragraph.

96. As set forth above, Wright Medical has been aware of each of the Conformis Patents. It has known about the '304 Patent since at least 2013 when Conformis had to sue Wright for infringing the '304 Patent. Wright Medical knew about the remaining Conformis Patents since 2015, when it entered the 2015 License Agreement and obtained a limited right to use the Conformis Patents. As a Conformis licensee, it was in Wright Medical's interest to ensure it was aware of all patents owned by or issued to Conformis, particularly those covering PSI. Wright Medical was also required by the 2015 License Agreement to determine which of its products practiced the Conformis Patents and mark those products accordingly.

97. Moreover, Wright Medical has been aware of each of the Conformis Patents since at least March of 2019, when Wright Medical's affiliate, Tornier SAS, submitted an information disclosure statement in United States Patent Application No. 15/024747, which application eventually issued as Tornier's '993 Patent. That information disclosure statement listed each of the Conformis Patents.

98. Wright Medical's direct and indirect infringement of the Conformis Patents has been willful. Wright Medical knew about each of the Conformis Patents—having even been sued for infringing the '304 Patent. And it knew that its right to use the Conformis Patents was specifically limited to foot- and ankle-

related products. Wright Medical knew its use of the Conformis Patents in shoulder-related products was beyond the scope of the 2015 License Agreement, which was carefully negotiated to resolve the parties' 2013 lawsuit. Therefore, Wright Medical knew that its Accused Systems were not licensed and infringed Conformis's Patents.

## **IX. PRAYER FOR RELIEF**

WHEREFORE, Conformis requests entry of judgment in its favor and against Wright Medical as follows:

99. Entry of judgment holding Wright Medical liable for infringement of the Conformis Patents;

100. An order permanently enjoining each Defendant, its officers, agents, servants, employees, attorneys and affiliated companies, its assigns and successors in interest, and those persons in active concert or participation with it, from continued acts of infringement of the Conformis Patents;

101. An order awarding Conformis statutory damages and damages according to proof resulting from Wright Medical's infringement of the Conformis Patents, together with prejudgment and post-judgment interest;

102. Trebling of damages and pre-judgment interest under 35 U.S.C. § 284 in view of the willful and deliberate nature of Wright Medical's infringement of the Conformis Patents;

103. An order awarding Conformis its costs and attorneys' fees under 35 U.S.C. § 285; and

104. Any and all other legal or equitable relief as may be available under

law and which the Court may deem proper.

**X. JURY DEMAND**

Conformis hereby demands trial by jury in this action on all issues so triable.

ASHBY & GEDDES

*/s/ Andrew C. Mayo*

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